UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,054	06/02/2000	Peter D. Hill	98-37	5574

30031 7590 09/21/2004

MICHAEL W. HAAS, INTELLECTUAL PROPERTY COUNSEL
RESPIRONICS, INC.
1010 MURRY RIDGE LANE
MURRYSVILLE, PA 15668

EXAMINER	
EREZO, DARWIN P	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,054	HILL ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5 and 7-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,041,780 to Richard et al. in view of US 5,794,615 to Estes, as evidenced by US 6,253,765 to Hognelid et al.

3. As to Claim 1, Richard teaches a method of adjusting a volume of a fluid supplied to a patient, the method comprising the steps of: supplying a plurality of volumes of fluid to a patient during a like plurality of inspiratory phases of a respiratory cycle of such a patient, each volume of fluid being supplied at inspiratory positive airway pressure during a corresponding inspiratory phase (col. 4, lines 35-42); determining, for each inspiratory phase, a volume of fluid received by such a patient; determining an average volume of fluid received by such a patient from the volumes of fluid received by such a patient during the plurality of inspiratory phases; comparing the average volume to a predetermined target volume; and adjusting the inspiratory positive airway pressure based on the comparison (col. 4, line 28 – col. 5, line 17). Richard is silent with regards to the average volume being calculated irrespective of time. Estes teaches a method of adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by

comparing the tidal volumes that are irrespective of time (average of 3 breathes; col. 18, lines 7-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the method steps of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

4. As to Claim 2, Richard teaches a method wherein estimating, for each inspiratory phase, a volume of fluid leaked from a breathing gas supply system that supplies such a patient with the plurality of volumes of fluid, and combining, for each inspiratory, the volume of fluid leaked and the volume of fluid supplied to such a patient to obtain the volume of fluid received by such a patient (col. 4, lines 45-50).

5. As to Claims 3 and 4, Richard teaches a method of adjusting the IPAP level so as to gradually conform an actual volume to a target volume. Therefore, this method would inherently perform the steps recited in the claim.

6. As to Claim 5, Richard teaches all the limitations of the claim except for the predetermined pressure of approximately 0.1 cm H2O. However, Richard does teach thus use of using a predetermined pressure of approximately 1 cm H2O. Therefore, it would have been obvious to one of ordinary skill in the art to use any predetermined pressure depending on the intended therapy and the size of the patient. Furthermore,

the Applicant has not disclosed that the specific predetermined pressure solves any stated problems or is for any particular purpose.

7. As to Claims 7-9, Richard teaches a method of supplying fluid to a patient, comprising: supplying a first volume of fluid to a patient at a first inspiratory positive airway pressure; determining, for the first volume of fluid supplied to such a patient, a first volume of fluid received by such a patient; supplying a second volume of fluid to such a patient at the first inspiratory positive airway pressure; determining for the second volume of fluid supplied to such a patient, a second volume of fluid received by such patient; determining, based on the first and the second volumes of fluid received by such a patient, a first average volume of fluid received by such patient. Though Richard does not specifically teach comparing the first average volume to a predetermined target volume and adjusting the first inspiratory positive airway pressure to a second inspiratory positive airway pressure based on the comparison in the comparing step, it would have been an obvious step because Richard teaches the step of comparing the average volume after a certain time frame and adjusting the inspiratory positive airway pressure based on the comparison. Therefore, the method step of Richard is capable of performing the recited step, including a third volume or a fourth volume. Furthermore, the inspiratory airway pressures can be the same depending on the patient.

Richard is silent with regards to the average volume being calculated irrespective of time.

Estes teaches a method of adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by comparing the tidal volumes that are irrespective of time (average of 3 breathes; col. 18, lines 7-8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the method steps of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

8. As to Claims 10 and 11, it is inherent in the method steps of Richard to have the second inspiratory positive airway pressure be greater than the first inspiratory positive airway pressure if the average volume is lower than the target volume or to have the inspiratory positive airway pressure be the same as the first inspiratory positive airway pressure if the average volume is within the target volume.

9. As to Claim 12, Richard teaches a method of performing leak estimation (col. 4, lines 45-48).

10. As to Claim 13, Richard teaches an apparatus for supplying fluid to a patient , the apparatus comprising a pressure generator system **14** adapted to provide a flow of fluid at one of a variable pressure and a variable flow; a patient circuit **18** operatively coupled to the pressure generating system to deliver the flow of fluid to a patient; an interface

device **16** operatively coupled to the patient circuit to communicate the flow of fluid to an airway of a patient; at least one sensor **26** operatively coupled to the interface device to detect a parameter indicative of a volume of fluid delivered to such a patient; and a controller **24** operatively coupled to the sensor and the pressure generating system, wherein the controller determines a volume of fluid received by the patient for each inspiratory phase, determines an average volume of fluid over a plurality of inspiratory phases; compares the average volume of fluid to a predetermined target volume, and causes the pressure generating system to adjust one a pressure and a rate of flow of the fluid based on the comparison (col. 4, line 28 – col. 5, line 17).

Richard is silent with regards to the average volume being calculated irrespective of time.

Estes teaches a device for adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by comparing the tidal volumes that are irrespective of time (average of 3 breathes; col. 18, lines 7-8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the device of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

11. As to Claim 14, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average volume is less than a predetermined target volume; decrease the pressure when the average volume is greater than the predetermined target volume; and maintain the pressure when the average volume is within the target volume (col. 4, lines 17-28).

12. As to Claim 15, Richard teaches a controller that is fully capable of performing the recited limitation.

13. As to Claim 16, Richard teaches an apparatus wherein the pressure generating system includes a fluid source that outputs the flow of fluid and a pressure regulator (col. 3, line 66 – col. 4, line 4).

14. As to Claim 17, Richard teaches an apparatus wherein the at least one sensor includes a flow sensor **26** and a pressure sensor **28** and wherein the controller estimates fluid leakage (col. 4, line 45-48).

15. As to Claim 18, it is inherent for the operation of the device of Richard to perform the recited limitation as disclosed in col. 4, lines 43-57.

16. As to Claim 19, Richard teaches an apparatus for supplying fluid to a patient comprising a pressure generating means **14**, delivering means **18**, interfacing means **16**, sensing means **26**, and processing means **24** (col. 4, line 28 – col. 5, line 17). Richard is silent with regards to the average volume being calculated irrespective of time. Estes teaches a method of adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by comparing the tidal volumes that are irrespective of time (average of 3 breathes; col. 18, lines 7-8). Therefore, it would have been obvious

to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the device of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

17. As to Claim 20, Richard teaches a processing means that performs the recited function in col. 4, lines 42-57.

18. As to Claim 21, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average volume is less than a predetermined target volume; decrease the pressure when the average volume is greater than the predetermined target volume; and maintain the pressure when the average volume is within the target volume (col. 4, lines 17-28).

19. As to Claim 22, it is inherent for the operation of the device of Richard to perform the recited limitation as disclosed in col. 4, lines 43-57.

As to Claim 23, Richard teaches an apparatus comprising supplying means **14**, inspiratory volume determining means **26**, average volume determining means (through processor **24**), comparing means and adjusting means (col. 4, line 28 – col. 5, line 17). Richard is silent with regards to the average volume being calculated irrespective of time. Estes teaches a method of adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by comparing the tidal volumes that are irrespective of

time (average of 3 breathes; col. 18, lines 7-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the device of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

20. As to Claim 24, Richard teaches an inspiratory volume determining means including leak estimating means (col. 4, lines 42-57).

21. As to Claim 25, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average volume is less than a predetermined target volume; decrease the pressure when the average volume is greater than the predetermined target volume; and maintain the pressure when the average volume is within the target volume (col. 4, lines 17-28).

22. As to Claim 26, Richard teaches a processor that is fully capable of performing the recited limitation.

As to Claim 27, Richard teaches an apparatus comprising supplying means **14**, determining means, averaging means, comparing means, and adjusting means (through processor **24**; col. 4, line 28 – col. 5, line 17). Richard is silent with regards to the average volume being calculated irrespective of time. Estes teaches a method of adjusting a volume of a fluid supplied to a patient, in which the volume is adjusted by

comparing the tidal volumes that are irrespective of time (average of 3 breathes; col. 18, lines 7-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the average volume irrespective of time, as taught by Estes, because it allows the system to detect hypopnea and to adjust the flow of fluid accordingly. Furthermore, it would have been obvious to use an average volume that is calculated irrespective of time in the device of Richard since it is known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21.

23. As to Claims 28 and 29, Richard teaches an apparatus that compares the average volume after a certain time frame and adjusting the inspiratory positive airway pressure based on the comparison. Therefore, the apparatus of Richard is fully capable of performing the recited function, including a third volume or a fourth volume. Furthermore, the inspiratory airway pressures can be the same depending on the patient.

24. As to Claims 30 and 31, Richard teaches an apparatus of adjusting the IPAP level so as to gradually conform an actual volume to a target volume. Therefore, the device would inherently perform the recited limitation.

25. As to Claim 32, Richard teaches an inspiratory volume determining means including leak estimating means (col. 4, lines 42-57).

Allowable Subject Matter

26. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

27. Applicant's arguments filed 6/8/04 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references or that combining the references will render the reference inoperable, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known in the art that determined or regulated volume is usually stipulated in volume per breath (tidal volume) or average volume received per unit of time (minute volume), as evidenced by Hognelid in col. 1, lines 19-21. Therefore, switching between average tidal volume or average minute volume will not render the reference inoperable since either method of calculating average volume will still provide a value that can be compared to a predetermined target value in order to adjust the volume supplied to the patient.

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

de

GLENN K. DAWSON
PRIMARY EXAMINER